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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,633	11/25/1997	ELAZAR RABBANI	ENZ-53	4639

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/978,633	RABBANI ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3-25-09 and 8-21-09.*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *245-248,251,253,261-265,306 and 307* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *245-248,251,253,261-265,306 and 307* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-25-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communications filed 3-25-09 and 8-21-09.

Claims 245-248, 251, 253, 261-265, 306 and 307 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of a linear nucleic acid complementary to a sequence of said specific nucleic acid component, an epitope on the surface of said cell of interest, and polymer in the reply filed on 8-21-09 is acknowledged. The traversal is on the ground(s) that searching all of the domains, binders, etc would not constitute an undue burden and the different binders claimed share a common feature in they all contain at least one domain, and Applicant also suggests that the terms “matrix” and “polymer" are exchangeable. This is not found persuasive because the searches required for the different and distinct groups would pose a serious burden because each of the genera claimed is quite expansive, and the corresponding data bases that would be required to be searched would in turn be expansive, thereby posing a serious burden on the searching facilities and on the examiner (e.g. among the expansive genera claimed, include these: *any protein that binds to any ligand of any modified nucleotide in a specific nucleic acid component*;; *any virus particle or viral fragment that binds to a receptor*; *any hormone specific to a receptor*; *any lectin specific for a sugar*…). What’s more, these different groups, including the different binders claimed, are chemically,

functionally, biologically and structurally different and distinct and one does not render the other obvious.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims, or parts of the claims drawn to an invention nonelected with traverse in the reply filed on 8-21-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 245-248, 251, 253, 261-265, 306 and 307 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 275, 289, 290, 296-301 of copending Application No. 08/978,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods and cell delivery compositions comprising covalently bound polynucleotides, targeting ligands and polypeptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No arguments have been made concerning this rejection.

Claims 245-248, 251, 253, 261-265, 306 and 307 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/929,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to cell delivery compositions comprising covalently bound polynucleotides, targeting ligands and optionally further comprising polypeptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No arguments have been made concerning this rejection.

Rejections Necessitated by Amendments

Applicant's arguments with respect to claims 245-248, 251, 253, 261-265, 306 and 307 have been considered but are moot in view of the new ground(s) of rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 245-248, 251, 253, 261-265, 306 and 307 are rejected under 35 U.S.C. 103(a) as being unpatentable over Priest (USPN 5,391,723) and Curiel et al. (U.S. Patent 5,521,291), the combination in view of Elliott et al (USPN 5,837,489).

The claims are drawn to nucleic acid components, compositions, kits, a method of introducing nucleic acid components into a cell, and target cells which comprise the nucleic acid components, which nucleic acid compositions comprise a non-natural entity comprising a nucleic acid domain which is complementary to a nucleic acid component which directs synthesis of a nucleic acid product, and which non-natural entity further comprises at least one domain to a cell of interest, which is optionally an antibody that recognizes an epitope on a cell surface, and which non-natural entity further comprises a binder which is optionally a polymer.

Priest (USPN 5,391,723) teaches nucleic acid constructs for target cell delivery comprising a nucleic acid domain linked covalently to a targeting protein domain which is optionally an antibody which is targeted to a target cell epitope, which antibody is optionally monoclonal or polyclonal, and which nucleic acid is linked either directly to the antibody or via a linker, and which nucleic acid conjugates are optionally single or double stranded (see the abstract, col. 2, 6-9, 17-18).

Curiel et al. (U.S. Patent 5,521,291) teach methods, compositions, target cells for delivering compositions to cells in vitro and in vivo, and kits for target cell delivery, which compositions comprise a construct having at least one terminus comprising a polynucleotide tail hybridized to a complementary polynucleotide and an antibody bound to the hybridized polynucleotide (e.g. ribozymes attached to antibodies, or viral nucleic acids for target cell delivery in combination with antisense for target gene inhibition, target cell ligands), and which nucleic acid compositions optionally comprise a domain to a specific nucleic acid component and a domain to a cell of interest, and a different, specific nucleic acid desired to be delivered to said cell, and optionally comprising a binder which is a polymer, or one which mediates ligand binding to a receptor, including lectins, antigens and other receptors (see esp. the abstract; Fig. 1; col. 3-11; 13; 16; example 6, col. 24-29; claims 3, 5, 6, 14 and 15).

The primary references do not teach a nucleic acid domain which is complementary to a linear nucleic acid, and which domain directs synthesis of a nucleic acid product.

Elliott et al (USPN 5,837,489) teach the design, transfection into target cells and expression of nucleic acid constructs which optionally comprise expression vectors, which are optionally closed plasmids or linear constructs, and which direct synthesis of nucleic acid products (see esp. paragraphs 53 and 54).

It would have been obvious to design and use a non-natural construct comprising a nucleic acid linked to a targeting protein, and optionally via a linker which also comprises a polymer, and which nucleic acid is complementary to a second nucleic acid, because Priest and Curiel taught nucleic acid constructs comprising self-complementary polynucleotides wherein one of the nucleic acid strands is optionally covalently linked to a targeting protein which is optionally an antibody directed to a target cell epitope for target cell delivery, and is optionally linked via a linker or polymer. One would have been motivated to design and use this composition for enhancing target cell delivery of a nucleic acid construct, relying on the bound targeting protein. It would have been obvious to replace one of complementary (oligonucleotide) nucleic acid strands taught by Priest or Curiel with a longer nucleic acid which directs the synthesis of a nucleic acid product because this allows for the targeting of an expression construct to a desired target cell, whereby a nucleic acid product is expressed rather than solely utilizing the target constructs for delivery of target gene inhibition constructs. To replace one of the strands of a double stranded oligonucleotide delivery construct with a longer nucleic acid strand that directs synthesis of a nucleic acid product would have been a matter of design choice and would have required

routine experimentation taught previously in the art, as evidenced by the teachings of Priest and Curiel.

One would have been motivated to have one of the nucleic acid strands as an expression unit that allows for the synthesis of a nucleic acid product because this approach logically allows for multiple or alternative uses of a targeting nucleic acid construct, including but not limited to the expression of a recombinant (e.g. therapeutic) gene product within or in the vicinity of a desired target cell, and also allows for the expression of either inhibitory nucleic acids or recombinant proteins at the site of the target cell, increasing their concentration at the target cell site. One of skill in the art would have reasonably expected that the targeting constructs previously taught by Priest and Curiel would provide for enhanced target cell localization of the nucleic acids, thereby increasing the concentration of nucleic acids at the target cell site, in turn allowing for the expression of a desired nucleic acid product in or near the target cell, and allowing for enhanced delivery of therapeutic molecules at a desired target cell site in the body.

For these reasons, the instant invention would have been obvious to one of skill in the art at the time of the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore, can be reached on (571) 272-2914. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
11-20-09

/Jane Zara/

Primary Examiner, Art Unit 1635